**PrescQIPP Standard Terms of Agreement for Primary Care Rebate Schemes**

Scheme Details

Company: [ ]

Scheme name: [ ]

Company contact name and email address: [ ]

Generic company contact e-mail (we require a generic email in case of personnel changes in the company): [ ]

Generic Freedom Of Information / queries contact e-mail (we require a generic email in case of personnel changes in the company): [ ]

Is the Integrated Care Board (ICB)/Health Board (HB) required to sign up to ALL products within the rebate scheme presented here? [Y/N]

Frequency of payments: [ ]

Length or expiry of scheme: [ ]

Notice period for ICB/HB: [ ]

Notice period for Supplier: [ ]

Other details around administering the scheme (e.g. payment processes, deadlines and timescales):

[ ]

If the scheme requires any data other than standard primary care prescribing data (e.g. BSA data or ePACT) please provide detail, and expected process below:

[ ]

If the scheme requires any involvement or administration by third parties on behalf of the supplier, please detail below:

[ ]

Information to support resilience of supply of relevant products (the purpose of this question is to anticipate and ascertain whether any increase in demand across the whole NHS for a particular product, would result in problems with supply. To this end, we are interested in your current market sales as a proportion of the total market, your stock holding in weeks currently and how long your manufacturing lead time is. Information on these points (in confidence) would be very helpful):

[ ]

Details of presentations included in the scheme:

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Generic name** | **Brand name** | **BNF presentation code** | **Pack size** | **Therapeutic class** | **List price** | **% Rebate** | **Net price** |
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**PISGRB Guidance Note –** if the financial offering within the scheme is a standard x% rebate the **% Rebate** column will be filled in. If the scheme is a commitment to a set price then **% Rebate** will be populated with **N/A** to indicate this, and the set rebate price populated in the final (Net Price) column.

### The following terms overleaf have been adopted without amendment from the PrescQIPP CIC Pharmaceutical Industry Scheme Governance Review Board’s Standard Terms of Agreement for Primary Care Rebate Schemes Template v3.7

### Definitions and interpretations

* 1. In these Terms the following expressions shall, unless otherwise specified or the context otherwise requires, have the following meanings:

**“Affiliate”** means any company which (directly or indirectly) controls, is controlled by and/or is under common control with the Supplier.

**“Applicable Laws”** means all applicable laws, rules, regulations, including case law, as well as any guidance, guidelines and requirements of any regulatory authorities and any industry codes of practice in effect from time to time applicable to the activities performed under this PCRS Agreement.

**“ICB / HB Representative”** means the party appointed by the ICB / HB and notified to the Supplier pursuant to Clause 3 below, the first such person as set out in Schedule 1 to this PCRS Agreement.

**“Effective Date”** means the agreed specified start date of the scheme, which can include past or future dates.

**“Medicine”** means the pharmaceutical or medicinal product supplied by the Supplier for the treatment of a Patient or Patients that is the subject of a Primary Care Rebate Scheme.

**“Force Majeure”** means any circumstances beyond the reasonable control of either party (including, without limitation, any strike, lock-out or other industrial action).

**"Indirect Taxes"** means value added taxes, sales taxes, consumption taxes and other similar taxes.

**“NHS Dispensing Contractors”** means a community pharmacy business, a dispensing doctor, an appliance supplier or stoma provider with a contract to provide a NHS dispensing service.

**“NHS Associated Parties”** means parties considered part of the NHS and who require access to Supplier Confidential Information in order to perform their functions in relation to the NHS, including: employees of the ICB/HB; GPs and other NHS employed contractors working with the ICB/HB (such as CSUs, or PrescQIPP); NHS England, the Department of Health and Social Care.

**“Party or Parties”** means the ICB, CSU or HB and the Supplier identified within this document that enter into a PCRS Agreement.

**“Patient”** means a person who receives treatment or care from the ICB/HB and/or paid for by the ICB/HB or where the ICB/HB reimburses the cost of treatment of Medicines and Devices.

**“PCRS Agreement”** means the agreement constituted by these Terms and the contents of the PCRS Scheme Details.

**“Primary Care Rebate Scheme (PCRS)”** means a scheme proposed by pharmaceutical companies and operated by NHS ICBs/HBs to improve the cost effectiveness of medicines dispensed in primary care.

**“Quarter”** means a calendar quarter within the Term (i.e. Jan-Mar, Apr-Jun, Jul-Sep and Oct-Dec)

**“Rebate”** means the retrospective discount to the NHS list price, or specified reduced price, of the Medicine or Device offered by the Supplier to the ICB/HB.

**“Scheme Details”** means the individual scheme components outlined in the Scheme Details in the preceding section.

**“Supplier”** means the pharmaceutical company offering the PCRS for the Medicine that may be purchased or paid for by the ICB/HB for use in the treatment of a Patient.

**“Supplier Confidential Information”** means information marked by the Supplier as confidential due to commercial sensitivity and shall in all cases include the amount of the Rebate applicable to a Medicine or Device. This content is normally defined by the redacted sections in the redacted contract supplied by the supplier after the assessment is completed.

**“Supplier’s Representative”** means a party appointed by the Supplier and notified to the ICB/HB pursuant to Clause 3, the first such person as set out in Schedule 1 to this PCRS Agreement.

**“Supply”** means the supply of the Medicine for the treatment of Patients within the ICBs/HBs geographical area of responsibility.

**“Terms”** means the standard terms for the operation of Primary Care Rebate Schemes set out in this document.

**“Writing”** means any communication in writing including electronic mail and “Written” shall be construed accordingly.

* 1. In these Terms unless otherwise specified or the context otherwise requires:
     1. words importing the singular only shall include the plural and vice versa;
     2. reference in these Terms to a provision of a statute shall be construed as a reference to that provision as amended, re-enacted or extended at the relevant time;
     3. reference to a Clause means a Clause of these Terms;
     4. the headings in these terms are for convenience only and shall not affect their interpretation.

### Cost Reduction Mechanisms

* 1. The Supplier undertakes that any usage data received pursuant to this PCRS Agreement will be used for the sole purpose of assisting the calculation of any Rebate due to the ICBs/HBs for the relevant quarter.

### Representatives

* 1. The representatives of the Parties for the purposes of administering the PCRS Agreement shall be as notified in Writing by one Party to the other from time to time.
  2. All queries and day to day communications regarding the operation of a PCRS Agreement shall be dealt with by the Parties’ representatives in the first instance and the ICBs/HBs Representative and the Supplier’s Representative shall directly liaise for the purposes of monitoring and reviewing the operation and performance of the PCRS Agreement.

### Limitation of Liability

* 1. Nothing in this PCRS Agreement limits or excludes a Party's liability for: death or personal injury arising out of negligence; for fraud, fraudulent misrepresentation, criminal acts; or where such a limitation or exclusion would be contrary to law.
  2. Subject to clause 4.1 of these Terms neither Party nor any of its Affiliates shall be liable to the other Party or its Affiliates for any indirect, special, exemplary or consequential loss of any kind, whether in contract (including for damages for any deliberate repudiatory acts), delict or tort (including negligence), for breach of statutory duty, or otherwise.

### Freedom of Information and Data Protection

* 1. Any personal data processed under this PCRS Agreement must be kept secure at all times and only be used for the purposes of this PCRS Agreement.
  2. Each party shall at its own expense, ensure that it complies with and reasonably assists the other party to comply with the requirements of all legislation and regulatory requirements in force from time to time in the UK relating to the use of personal data, and the privacy of electronic communications, including, without limitation: (i) the Data Protection Act 2018 and any successor UK legislation; and, (ii) the retained EU law version of General Data Protection Regulation ((EU) 2016/679)  (UK GDPR), and (iii) the Privacy and Electronic Communications Regulations 2003 (SI 2003/2426) and  the guidance and codes of practice issued by the Information Commissioner or other relevant regulatory authority and applicable to a Party.
  3. No Confidential Information relating to the identity, condition, medical treatment or history of a Patient will be provided to a Supplier further to a PCRS Agreement.
  4. The ICBs/HBs shall treat as confidential all Supplier Confidential Information and shall not disclose to any third party without the prior written consent of the Supplier any Supplier Confidential Information; provided that such undertaking will not apply where the information:
     1. is or becomes public knowledge other than by breach of this Clause 5;
     2. is in the possession of the ICB/HB without restriction in relation to disclosure before the date of receipt;
     3. is received from a third party who lawfully acquired it and who is under no obligation restricting its disclosure;
     4. is independently developed without access to the Supplier Confidential Information;
     5. to the extent that the ICB/HB is required to disclose such Supplier Confidential Information by law or any regulatory or government authority (but only to that extent) and provided that to the extent the ICB/HB is legally able to do so it shall (i) advise the Supplier as soon as reasonably practicable of any such legal requirement made of it by a regulatory or governmental authority to disclose Confidential Information, (ii) seek an opportunity for the Supplier to make representations to the regulatory or governmental authority and (iii) advise the regulatory or governmental authority of the confidential nature of the Supplier Confidential Information.
  5. The ICB/HB recognises the legitimacy of the value and detail of the Rebate being commercially sensitive and confidential.
  6. Nothing contained in this Clause 5 shall prevent the ICB/HB from disclosing any Supplier Confidential Information wherever disclosure is required by virtue of the ICBs/HBs status as an NHS entity to a department, office or agency of the ICBs/HBs Government or to any other NHS Associated Parties; Provided that the ICB/HB shall require the recipient of such Supplier Confidential Information to accept an obligation of confidentiality in relation to such Supplier Confidential Information in terms no less onerous than contained in these Terms.
  7. Nothing whether expressly provided in the PCRS Agreement, or otherwise implied, shall preclude the ICB/HB from making public under the Freedom of Information Act (2000) and/or any codes or regulations applicable from time to time relating to access to public authorities’ information (“FOI”), details of all matters relating to the PCRS Agreement unless:

(i) such information constitutes Supplier Confidential Information contained within the Scheme Details, and for the avoidance of doubt is supported by a redacted non-confidential version of this PCRS Agreement;

(ii) the disclosure of such details would or would be likely to prejudice substantially the commercial interests of any person (including but not limited to the Supplier or any ICB/HB);

or (iii) such details fall within any other exemption under FOI provided always that application of any such exemption referred to at (i), (ii), (iii) above shall be at the sole discretion of the ICB/HB.

* 1. The ICB/HB is under no obligation to notify the Supplier of intended disclosures under FOI unless the request for information or intended disclosure constitutes Supplier Confidential Information.
  2. The Supplier shall commit to:
* provide a redacted non-confidential version of the PCRS Agreement to support the avoidance of any doubt around what constitutes Supplier Confidential Information, in advance of signing the PCRS Agreement.
* transfer any FOI request from a third party for information relating to the PCRS Agreement to the ICB/HB as soon as practicable after receipt and in any event within five working (5) days of receiving such request for information;
* provide reasonable assistance as may be required by the ICB/HB to enable the ICB/HB to comply with its obligations under FOI.

### Assignment / Assignation and Affiliates

* 1. The ICB/HB, acting reasonably, shall consider any application for assignment or assignation of the PCRS Agreement to a third party by the Supplier where the Supplier intends to assign or sell its rights in relation to the supply of the Medicine to such third party.
  2. The PCRS Agreement shall automatically devolve to the statutory successors of the ICB/HB and the ICB/HB shall give reasonable notice to the Supplier of such changes.

### Force Majeure

* 1. If either Party is affected by Force Majeure it shall promptly notify the other Party of the nature and extent of the circumstances in question.
  2. Neither Party shall be deemed to be in breach of these Terms, or otherwise be liable to the other, for any delay in performance or the non-performance of any of its obligations under the PCRS Agreement, to the extent that the delay or non-performance is due to any Force Majeure and the time for performance of that obligation shall be extended accordingly.

### Unresolved Matters

* 1. It is the intention of the ICB/HB and the Supplier to resolve any dispute or difference between them by mutual dialogue consistent with the overall aims and objectives of the PCRS Agreement. Any matter under a PCRS Agreement, either in relation to its interpretation or application or otherwise relating to the rights and obligations of the ICB/HB and the Supplier shall be referred to their respective Chief Executives or to the duly authorised persons designated by the Chief Executives if the matter cannot be resolved by the ICBs/HBs Representative and the Supplier’s Representative in the first instance. The matter shall be referred within two months of the date that the ICB/HB or the Supplier first identify the matter as unresolved. Dialogue in the form of discussions, correspondence and minutes of meetings shall be confidential.
  2. The ICB/HB and the Supplier and where relevant their Chief Executives or representatives shall meet to consider the possible avenues for resolution of any dispute or difference. Prior to such meetings the ICB/HB and the Supplier may take expert advice on matters in dispute as appropriate.
  3. If agreed between the ICB/HB and the Supplier and where relevant their Chief Executives or representatives, they shall be free at any time to refer an unresolved matter to an independent review panel composed of expert or experts who have appropriate management, technical, professional and/or business skills to independently report on the dispute. Any conflicts such experts may have must be declared. The remit of such expert or experts and the reliance to be placed on any such report, the deadlines that apply to hearings of the panel and to the production of its report, the sharing of costs of the panel and the action to be taken in light of any such report shall be determined by the ICB/HB and the Supplier and where relevant their Chief Executives or representatives.

1. General
   1. No variation of these Terms shall be binding unless agreed in Writing between the ICBs/HBs Representative and the Supplier’s Representative.
   2. A notice required or permitted to be given by either Party to the other under these Terms or the PCRS Agreement shall be in Writing delivered personally, sent by first class recorded delivery post or sent by email to the ICBs/HBs Representative (for the ICB/HB) and the Supplier’s Representative (for the Supplier). Notices shall be addressed to that other Party at its registered office or principal place of business or such other address for receipt of notices (including email address) as either Party may previously have notified the other party in Writing. A notice shall be deemed to have been served:
      1. if personally delivered, at the time of delivery;
      2. if posted, at the expiration of forty-eight (48) hours after the envelope letter was delivered into the custody of the postal authorities; or
      3. if sent by email, on receipt of notification of delivery.
   3. No waiver by either party of any breach of the PCRS Agreement by the other shall be considered as a waiver of any subsequent breach of the same or any other provision.
   4. In the event of a material and / or repudiatory breach by either party, the innocent party will be entitled to terminate the PCRS Agreement with immediate effect on Written notice.
   5. In the event of insolvency of either Party the PCRS Agreement will be automatically terminated.
   6. If any provision of the PCRS Agreement is held by a court or other competent authority to be invalid or unenforceable in whole or in part the validity of the other provisions of these Terms and the remainder of the provision in question shall not be affected.
   7. The ICB/HB is under no direct or indirect obligation to utilise the rebate for a specific purpose.
   8. The ICB/HB acknowledges that prescribing decisions made by individual clinicians will be determined by the clinical needs of the Patients. The ICB/HB will remain free at all times to use and promote the use of any treatment. The ICB/HB is not under any obligation to endorse or increase the usage of the Medicine or Device or any other product of the Supplier. The Parties are not agreeing that the Medicine or Device either is or is not medically superior to any other product.
   9. The Supplier and the ICB/HB agree that this PCRS agreement is not a reward or incentive for an individual’s past, present or future willingness to prescribe, supply, administer, recommend, buy or sell the Medicine or Device or any other product sold or provided by the Supplier or as an incentive to grant an interview for sales or marketing purposes.
   10. The supplier warrants and undertakes to the ICB/HB that:
       1. it will comply with applicable laws, regulations, codes and sanctions relating to anti-bribery and anti-corruption including but not limited to the Bribery Act 2010 (”Anti-Bribery Law”);
       2. it will have and operate an Anti-Bribery Policy which is in accordance with the Guidelines referred to in The Bribery Act 2010;
       3. it will procure that any person who performs or has performed services for or on its behalf (”Associated Person”) in connection with this PCRS Agreement complies with this Clause;
       4. it will not enter into any agreement with any Associated Person in connection with this PCRS Agreement, unless such agreement contains undertakings on the same terms as contained in this Clause;
       5. it has and will maintain in place effective accounting procedures and internal controls necessary to record all expenditure in connection with this PCRS Agreement;
       6. from time to time, at the reasonable request of the ICB/HB, it will confirm in writing that it has complied with its undertakings under Clauses 9.10.1 to 9.10.5 and will provide any information reasonably requested by the ICB/HB in support of such compliance
       7. it shall notify the ICB/HB as soon as practicable of any breach of any of the undertakings contained within this Clause of which it becomes aware.
   11. Breach of any of the undertakings in clause 9.10 shall be deemed to be a material breach of the PCRS Agreement and the ICB/HB may terminate this PCRS Agreement with immediate effect.
   12. If the Supplier is charged under The Bribery Act 2010 the ICB/HB may terminate this PCRS Agreement with immediate effect.
   13. The Supplier shall indemnify the ICB/HB in full from and against any other loss sustained by the ICB/HB in consequence of any breach of clauses 9.10- 9.12, whether or not the PCRS Agreement has been terminated.
   14. Nothing is intended to, or shall be deemed to, establish any partnership or joint venture between the Parties, constitute any Party the agent of the other Party, nor authorise a Party to make or enter into any commitments for or on behalf of the other party.
   15. The rebate payment is exempt of any application of VAT.

### Governing Law

* 1. These Terms and any PCRS Agreement shall be governed and construed in accordance with the laws of the ICBs/HBs country and the parties hereby submit to the non-exclusive jurisdiction of that country’s courts.

**Intending to be legally bound, the Parties have caused this Agreement to be executed by their duly authorised officers or directors as of the Effective Date.**

**Contract Effective Date [**detail**]**

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| --- | --- | --- | --- |
| **For [**Supplier**]** | | **For [**ICB/HB**]** | |
| **Signature:** |  | **Signature:** |  |
| **Printed Name:** |  | **Printed Name:** |  |
| **Title:**  **Date:** |  | **Title:**  **Date:** |  |

Second signature (if required)

|  |  |  |  |
| --- | --- | --- | --- |
| **For [**Supplier**]** | | **For [**ICB/HB**]** | |
| **Signature:** |  | **Signature:** |  |
| **Printed Name:** |  | **Printed Name:** |  |
| **Title:**  **Date:** |  | **Title:**  **Date:** |  |

**Schedule 1 - Contacts**

**ICBs/HBs Representative**

|  |  |
| --- | --- |
| **Function** |  |
| **Title** |  |
| **Address** |  |
| **Phone number** |  |
| **Email** |  |

**Supplier’s Representative**

|  |  |
| --- | --- |
| **Function** |  |
| **Title** |  |
| **Address** |  |
| **Phone number** |  |
| **Email** |  |